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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/089,265 | 03/27/2002 | Rajen Shah | 4-31158A | 2975 |

1095 7590 11/18/2003

THOMAS HOXIE
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER

JOYNES, ROBERT M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 11/18/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,265

Applicant(s)

SHAH ET AL.

Examiner

Robert M. Joynes

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment and Response filed on August 28, 2003.

Terminal Disclaimer

The terminal disclaimer filed on August 28, 2003 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent No. 6,565,883 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 is drawn to a *two pulse release* pharmaceutical composition comprising a composition according to claim 2. It is unclear how the composition is a *two pulse release* composition when nothing in Claim 2 or Claim 6 describe a two pulse release composition. Claim 2 is drawn to a composition in which one active is present in the core of the composition and nowhere in Claim 2 or 6 is a two pulse system described wherein the active agent is present in another portion of the composition other than the core to make it two pulse release. It is suggested to amend Claim 6 to include limitations as to how the composition achieves a two pulse release.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto et al. (US 5962535) in combination with Faour et al. (US 6004582).

Miyamoto teaches compositions for treating Alzheimer's disease wherein the compositions comprise idebenone in combination with an acetylcholinesterase inhibitor such as rivastigmine (Col. 2, lines 50-67; Col. 3, lines 1-65; Col. 9, lines 36-67; Col. 10, lines 1-2). The compositions are in the form of tablets, capsules and granules (Col. 10, lines 52-58). The tablets, capsules and granules can be coated for sustained release purposes and are manufactured by the known technology in the art (Col. 11, lines 5-10). Miyamoto does not expressly teach the exact formulation of the tablets, capsules and granules.

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Faour teaches a multi-layer composition comprising a core with an active agent; a semi-permeable membrane; a water-soluble coating; and an external coat that also contains an active for immediate release (Col. 3, line 49 – Col. 4, line 18). The compositions are suitable for a variety of drugs and pharmaceuticals, including antipsychotics and neuroleptics (Col. 13, lines 38-67). The device can be formulated to deliver the actives in a controlled manner in a variety of release mechanisms (Col. 5, lines 58-64).

Miyamoto and Faour do not expressly teach a coating thickness or an exact time for release of the drug from the composition once administered.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare a composition comprising rivastigmine and containing multiple layers for controlling the release of the active agent. Miyamoto teaches that rivastigmine can be formulated in tablets, capsules, and/or granules by techniques known in the art. Faour teaches one such composition that comprises a core with an active and multiple layers of coatings to control the release of the active.

One of ordinary skill in the art would have been motivated to do this deliver the active agent over an extended period of time to most effectively deliver the active agent. One would be motivated further to use such a composition to control the location of delivery of the active, i.e., deliver the drugs in the stomach or the colon.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments with respect to claims 2-6 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
November 14, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600